SECTION 15

BEST AVAILABLE TECHNOLOGY ECONOMICALLY ACHIEVABLE (BAT)

15.1 Introduction

Effluent limitations guidelines based on the best available technology economically achievable establish quantitative limits on the direct discharge of priority and nonconventional pollutants to waters of the United States. These limits are based upon the performance of specific technologies, but do not specify which technologies must be used to achieve compliance. BAT effluent limitations guidelines are applied to individual facilities through NPDES permits issued by EPA or authorized states under Section 402 of the CWA. Each facility then chooses its own approach to comply with its permit limitations.

The technology selected by the Agency to define the BAT performance may include end-of-pipe treatment, process changes, and internal controls, even when these technologies are not common industry practice. Section 7 provides an overview of the technologies assessed by the Agency.

BAT performance is established for groups of facilities (subcategories) with shared characteristics. Where a group of facilities demonstrates uniformly inadequate performance in controlling pollutants of concern, BAT may be transferred from a different subcategory or industrial category.

For Subcategory A and C facilities, EPA chose the BAT regulatory option to add organics and ammonia, revise COD to BPT limits, and clarify the monitoring requirements for cyanide. The Agency selected end-of-pipe advanced biological treatment with nitrification of ammonia as the technology basis for the BAT effluent limitations guidelines for Subcategory A and/or Subcategory C direct dischargers. The Agency chose to revise COD to BPT limits and withdraw cyanide limitations for Subcategory B and D facilities. The Agency selected BPT treatment technology (advanced biological treatment) as the basis for the BAT effluent limitations guidelines

for Subcategory B and/or Subcategory D direct dischargers. The rationale behind these selections is discussed in Section 11.

The following information is presented in this section:

- Section 15.2 reviews the subcategories and the pollutants to be regulated by BAT and presents the BAT effluent limitations guidelines; and
- Section 15.3 discusses BAT effluent limitations guidelines implementation with regard to point of application, NPDES permits, and monitoring and compliance issues.

15.2 Summary of the BAT Effluent Limitations Guidelines

15.2.1 Regulated Subcategories

Revised BAT effluent limitations guidelines are for Subcategories A, B, C, and D. As discussed in Section 4.3, Subcategories A, B, and C include wastewater discharges resulting from the manufacture of pharmaceuticals by fermentation, biological or natural extraction processes, and chemical synthesis processes, respectively. Subcategory D includes wastewater discharges resulting from mixing, compounding, and formulating of pharmaceutical products.

15.2.2 Regulated Pollutants

The BAT guidelines establish effluent limitations for the priority and nonconventional pollutants listed in Table 15-1 for direct dischargers in Subcategories A and C. EPA is not establishing BAT effluent limitations guidelines for Subcategory B and D operations except to set BAT COD limitations equivalent to the BPT COD limitations. Conventional pollutants are regulated under BPT and BCT and are not discussed here.

The revised BAT in this rulemaking clarifies existing in-plant cyanide limitations for Subcategory A and C facilities. Compliance monitoring for cyanide should occur immediately after cyanide

destruction, before commingling cyanide-bearing waste streams with non-cyanide bearing waste streams, unless a facility can demonstrate that cyanide is detectable at end-of-pipe. The 1983 cyanide limitations for Subcategory B and D direct dischargers are being withdrawn; these subcategories do not use or generate cyanide.

15.2.3 The BAT Effluent Limitations Guidelines

The BAT effluent limitations guidelines for each subcategory are based on a combination of long-term mean treatment performance concentrations and variability factors that account for day-to-day variation in measured treated effluent concentrations. Long-term mean treatment performance concentrations, discussed in Section 8, are target values that a facility's treatment system should achieve on a long-term, average basis. The variability factors, discussed in the Statistical Support Document(1), which is located in the Record for this rulemaking, represent the ratio of an elevated value, expected to occur only rarely, to the long-term mean. The purpose of the variability factor is to allow for variations in effluent concentrations that comprise the long-term mean. A facility that designs and operates its treatment system to achieve a long-term mean on a consistent basis should be able to comply with the daily and monthly limitations in the course of normal operations.

Table 15-2 presents the maximum daily and monthly average BAT effluent limitations guidelines for Subcategory A and C operations. These limitations were determined by multiplying the long-term means for each subcategory by the respective pollutant's 1-day and 4-day variability factors. A 4-day variability factor was used to develop the BAT monthly average limitations, with the exception of COD for which a 30-day variability factor was used. Table 15-3 presents the maximum daily and monthly average BAT COD effluent limitations guidelines for Subcategory B and D operations.

The BAT effluent limitations guidelines for acetonitrile, benzene, diethylamine, dimethyl sulfoxide, ethanol, n-heptane, methanol, methyl cellosolve, and triethylamine are based on the analytical method minimum level. The minimum level for a pollutant is the level at which an analytical system gives recognizable signals and an acceptable calibration point. For pollutants

with a long-term mean below the minimum level, typically in cases where treatment performance was established through data transfer, the final long-term mean was set at a value no lower than the minimum level for the pollutant. The final effluent limitations are determined by applying 1-day and 4-day variability factors to the final long-term means.

The BAT cyanide effluent limit, established in the 1983 Final Rule to be a daily maximum of 33.5 mg/L and a maximum monthly average of 9.4 mg/L for all subcategories, is not being revised for Subcategories A and C. The cyanide effluent limit is being withdrawn for Subcategories B and D because EPA has determined that cyanide is neither used nor generated by facilities with these subcategory operations.

15.3 Implementation of the BAT Effluent Limitations Guidelines

The BAT effluent limitations guidelines for Subcategory A and C operations are presented in Table 15-2. EPA is not establishing BAT effluent limitations guidelines for Subcategory B and D operations except to set a BAT COD limitation equivalent to the BPT COD limitation.

15.3.1 Establishing List of Pollutants for Compliance Monitoring

Permitting authorities should establish permit limitations and compliance monitoring requirements for each regulated pollutant, listed in Table 15-1, generated or used at a pharmaceutical manufacturing facility with Subcategory A and/or C operations. Limitations and routine compliance monitoring should not be required for regulated pollutants not generated or used at a facility. A determination that regulated pollutants are not generated or used should be based on a review of all raw materials and chemical processes used, considering resulting products and by-products. The determination that a regulated pollutant is not generated or used would need to be confirmed by annual chemical analyses of wastewater from each monitoring location. Such confirmation would be provided by an analytical measurement of a non-detect value.

Facilities discharging more than one regulated organic pollutant may monitor for a single surrogate pollutant to demonstrate an appropriate degree of control for a specified group of pollutants. For the purpose of identifying surrogates, pollutants are grouped according to treatability classes; Table 15-4 presents the treatability classes identified for advanced biological treatment, which is the BAT technology basis for organic pollutant limitations. For treatability classes with more than one possible surrogate pollutant, the analyte with the highest concentration or loadings should be chosen as the surrogate pollutant. Plants may monitor for a surrogate pollutant(s) only if they demonstrate that all other pollutants receive the same degree of treatment.

An individual plant may choose to demonstrate by selecting a monitoring pollutant for a given treatability class and maintaining documentation, including flow information and sampling results, that all pollutants in that treatability class receive equivalent treatment. The documentation is then submitted to the permit authority for approval.

15.3.2 Point of Application

The BAT effluent limitations for ammonia, COD, and the organic pollutants listed in Table 15-2 are end-of-pipe limitations and applicable to the final effluent at the point of discharge to waters of the United States, prior to non-process dilution waters. This compliance point is identical to the point used to demonstrate compliance with the BPT effluent limitations guidelines. Compliance monitoring for cyanide should occur in-plant, unless a facility can show a measurable amount of cyanide at end-of-pipe, instead of a non-detect in accordance with 40 CFR 403.6 (e)(2) and 403.6 (e)(4).

15.3.3 Permit Limitations

End-of-pipe permit limitations based on the BAT limitations for ammonia, COD, and organic constituents will be mass-based. Permit writers should use a reasonable estimate of process wastewater discharge flow and the concentration-based limitations listed in Table 15-2 to develop mass-based limitations for the NPDES permit.

"Process wastewater discharge" is defined by 40 CFR 122.2 to include wastewaters resulting from pharmaceutical products manufacturing that come in direct contact with raw materials, intermediate products, and final products, and surface runoff from the immediate process area that has the potential to become contaminated. Noncontact cooling waters, utility wastewaters, general site surface runoff, groundwater, and other nonprocess water generated on site are specifically excluded from this definition. The end-of-pipe limitations are developed from performance data at facilities which contain less than 25 percent nonprocess water through their biological treatment facility. Therefore, the end-of-pipe limitations for BAT apply to the pharmaceutical process wastewater allowing for up to 25 percent nonprocess wastewater. Non process flow in excess of 25 percent should be handled separately in establishing permit limits.

Using current facility information provided by the permit applicant, the permitting or control authority must determine the appropriate process wastewater discharge flow to use when developing mass-based limitations. In cases where the permit writer deems the process wastewater discharge flow claimed by industry to be excessive, he/she may develop a more appropriate process wastewater discharge flow for use in computing the mass-based limitations. The permit writer should review the following items to evaluate whether process wastewater discharge flow is excessive:

- Component flows, to ensure that the claimed flows are, in fact, process wastewater discharge flows as defined by 40 CFR 122.2.
- Plant operations, to ensure that sound water conservation practices are being followed. Examples include minimizing process water uses and reusing or recycling intermediate process waters or treated wastewaters at the process area and in wastewater treatment operations (pump seals, equipment and area washdowns, etc.).
- Barometric condenser use at the process level. Often, barometric condensers will generate relatively large volumes of slightly contaminated water. Replacing barometric condensers with surface condensers can reduce wastewater volumes significantly and result in collection of condensates that may be returned to the process.

Once the permit writer has reviewed the permit application, best professional judgment should be used to determine the facility's annual average wastewater discharge flow (i.e., the permit writer should consider only the sources of "process wastewater discharge," as defined previously, when determining the annual average process wastewater discharge flow allowing for up to 25 percent nonprocess wastewater). The annual average flow is defined as the average of daily flow measurements calculated over at least a year; however, if available, three to five years of data are preferable to obtain a representation of average daily flow(2).

If no historical or actual process wastewater flow data exist, the permitting authority is advised to establish a reasonable estimate of the facility's projected flow expected to be representative during the entire term of the permit. If a plant is planning significant production changes during the effective period of the permit, the permitting authority may consider establishing multiple tiers of limitations as a function of these production changes. Alternatively, a permit may be modified during its term, either at the request of the permittee or another interested party, or on EPA's initiative, to increase or decrease the flow basis in response to a significant change in production (40 CFR 124.5, 122.62). A change in production may be an "alteration" of the permitted activity or "new information" that could provide the basis for a permit modification (40 CFR 122.62(a)).

After determining the facility's annual average process wastewater flow, the permit writer would use this flow and not more than 25 percent nonprocess wastewater to convert the concentration-based limitations into mass-based limitations for ammonia, COD, and organic constituents for control at the end-of-pipe.

Additional detailed guidance on the establishment of permit limitations, including examples, is available in the Guidance for Implementing the Pharmaceutical Manufacturing Industry Regulations.

In-plant permit limitations for cyanide, based on the 1983 BAT limitations, will be concentration-based, and not converted to a mass basis. A concentration basis for cyanide offers a direct benchmark to assess whether the in-plant control technology is achieving the intended level. In-

plant wastestreams that require control may be generated or treated on a variable, batch basis, causing difficulty in establishing accurate mass-based permit limitations. Also, compliance is hindered, because the permitted facility cannot make a direct measurement to determine if its control technology is performing at the required level. Concentration-based permit limitations eliminate these problems and offer a direct measure of cyanide to both the permitting authority and the permitted facility that BAT performance levels are being achieved.

15.3.4 Monitoring and Compliance

Compliance monitoring for ammonia, COD, and all regulated organic constituents should be performed on a frequency basis established by the permit authority. EPA's monitoring costs for this regulation assumed compliance monitoring for ammonia and all regulated organic constituents on a weekly basis for Subcategory A and C facilities, and monitoring for COD on a daily basis for Subcategory A, B, C, and D facilities. The list of pollutants for which monitoring would be required at Subcategory A and C facilities includes all regulated constituents listed in Table 15-1 generated or used in pharmaceutical manufacturing processes at the facility. Based on the limitations, monitoring of ammonia, COD, and organic constituents generated or used in pharmaceutical manufacturing processes would occur prior to discharge to waters of the United States and before dilution with significant amounts of nonprocess waters.

Compliance with mass-based permit limitations is determined by multiplying the measured concentration of a regulated pollutant in the effluent sample by a conversion factor and by the total wastewater flow at the monitoring location during the effluent sampling period. Thus, the mass compliance value should be based on the total flow discharged on the day of sampling, not on the long-term average process water flow rate that provided the basis for establishing the permit limitations and standards.

Compliance monitoring for cyanide should occur in-plant, prior to commingling or dilution with non-cyanide-bearing wastewater, unless a facility can show end-of-pipe monitoring for cyanide is feasible. To show that end-of-pipe monitoring is feasible, the facility would need to demonstrate

compliance with cyanide limitations, adjusted as necessary to account for dilution with non-cyanide-bearing wastewater, at a level above the detection limit for cyanide.

The list of pollutants for which monitoring would be required should be updated based on consideration of raw material and process changes throughout the facility and an annual scan for all pollutants listed in Table 15-1. The annual scan should be performed at the compliance monitoring point(s) to identify any regulated pollutants in the wastewater. Permit monitoring and compliance should be required at all monitoring locations for all pollutants detected at any locations.

Dischargers must use the test methods promulgated at 40 CFR Part 136.3 or incorporated by reference in the tables of that part, when available, to monitor pollutant discharges from the pharmaceutical manufacturing industry, unless specified otherwise in part 439 (see 40 CFR 401.13) or by the permitting authority.

As a part of the final rule, EPA promulgated additional test methods for the pollutants to be regulated under Part 439 for which there are no test methods listed at 40 CFR Part 136.3. To support the Part 439 regulations at the time of proposal, EPA published test methods developed specifically for the pharmaceutical industry in a compendium entitled, "Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater," EPA-821-B-94-001. These test methods were discussed in the proposed rule and have been revised in response to public comment. The revised test methods are available for monitoring some pollutants covered by today's final rule. The revised test methods have been published in a revised compendium (the "Pharmaceutical Methods Compendium, Revision A;" EPA-821-B-98-016, 1998), with the same title as the proposed compendium.

In addition, EPA is allowing use of applicable drinking water methods that have been promulgated at 40 CFR Part 141 and use of ASTM Methods D3371, D3695, and D4763, for monitoring of the pollutants included in this rulemaking. The final rule allows for use of these additional test methods for several reasons: (1) it allows greater flexibility in monitoring; (2) it conforms use of methods in EPA's drinking water and wastewater programs; (3) it moves toward

a performance-based measurement system; and (4) it allows use of technical standards as contemplated by the National Technology Transfer and Advancement Act of 1995 (NTTAA).

Table 15-1

Pollutants Regulated Under BAT for Subcategories A and C

Priority Pollutants	
Benzene	Methylene chloride
Chlorobenzene	Phenol
Chloroform	Toluene
o-Dichlorobenzene (1,2-Dichlorobenzene)	Cyanide [(a)]
1,2-Dichloroethane	
Nonconventional Pollutants	
Ammonia	n-Hexane
Chemical Oxygen Demand (COD)	Isobutyraldehyde
Acetone	Isopropanol
Acetonitrile	Isopropyl acetate
n-Amyl acetate	Isopropyl ether
Amyl alcohol	Methanol
n-Butyl acetate	Methyl cellosolve
Diethylamine	Methyl formate
Dimethyl sulfoxide	Methyl isobutyl ketone (MIBK)
Ethanol	Tetrahydrofuran
Ethyl acetate	Triethylamine
n-Heptane	Xylenes

(a) Retaining cyanide effluent limits established in the 1983 final rule.

Table 15-2

BAT Effluent Limitations for Subcategory A and C Operations

Pollutant or Pollutant Property	BAT Effluent Limitations for In-Plant Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Cyanide [a]	33.5	9.4

(a) Cyanide effluent limit established in the 1983 final rule.

Pollutant or Pollutant Property	BAT Effluent Limitations for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L [a]
COD	1,675	856

(a) If these COD concentrations are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then effluent limitations for COD corresponding to the lower concentration values must be applied.

Pollutant or Pollutant Property	BAT Effluent Limitations for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Ammonia as N	84.1	29.4
Acetone	0.5	0.2
Acetonitrile	25.0	10.2
n-Amyl Acetate	1.3	0.5
Amyl Alcohol	10.0	4.1
Benzene	0.05	0.02
n-Butyl Acetate	1.3	0.5
Chlorobenzene	0.15	0.06
Chloroform	0.02	0.01
o-Dichlorobenzene	0.15	0.06
1,2-Dichloroethane	0.4	0.1
Diethylamine	250.0	102.0
Dimethyl Sulfoxide	91.5	37.5
Ethanol	10.0	4.1
Ethyl Acetate	1.3	0.5
n-Heptane	0.05	0.02

Table 15-2 (Continued)

Pollutant or Pollutant Property	BAT Effluent Limitations for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
n-Hexane	0.03	0.02
Isobutyraldehyde	1.2	0.5
Isopropanol	3.9	1.6
Isopropyl Acetate	1.3	0.5
Isopropyl Ether	8.4	2.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Methylene Chloride	0.9	0.3
Methyl Formate	1.3	0.5
MIBK	0.5	0.2
Phenol	0.05	0.02
Tetrahydrofuran	8.4	2.6
Toluene	0.06	0.02
Triethylamine	250.0	102.0
Xylenes	0.03	0.01

Table 15-3

BAT Effluent Limitations for Subcategory B and D Operations

Pollutant or Pollutant Property	BAT Effluent Limitations for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L [(a)]
Chemical Oxygen Demand (COD)	228	86

(a) If these COD concentrations are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then effluent limitations for COD corresponding to the lower concentration values must be applied.

Table 15-4

Surrogates for Subcategory A/C Direct Dischargers (Biotreatment)

Group	Compound	Surrogate (yes/no)
Alcohols	Ethanol	Yes
	Isopropanol	Yes
	Methanol	Yes
	Phenol	No
	Amyl alcohol	No
Aldehydes	Isobutyraldehyde	No
Alkanes	n-Heptane	Yes
	n-Hexane	Yes
Amides & Amines	Triethylamine	No
	Diethylamine	No
Aromatics	Toluene	Yes
	Xylenes	Yes
	Chlorobenzene	No
	o-Dichlorobenzene	No
	Benzene	No
Chlorinated Alkanes	Methylene chloride	Yes
	Chloroform	Yes
	1,2-Dichloroethane	Yes
Esters & Ethers	Ethyl acetate	Yes
	Tetrahydrofuran	Yes
	Isopropyl acetate	No
	n-Amyl acetate	No
	Isopropyl ether	No
	n-Butyl acetate	No
	Methyl formate	No
Ketones	Acetone	Yes
	MIBK	No
Miscellaneous	Ammonia (aqueous)	No
	Acetonitrile	No
	Dimethyl sulfoxide	No
	Methyl cellosolve	No

Yes - Surrogate pollutant for that group.
No - Not a surrogate pollutant for that group.

REFERENCES

1. U.S. EPA, Office of Water. Statistical Support Document for the Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Industry. EPA-821-B-98-007. U.S. Environmental Protection Agency, Washington, D.C., 1998.

2. U.S. EPA, Office of Water. Training Manual for NPDES Permit Writers. EPA 833-B-93-003, U.S. Environmental Protection Agency, Washington, D.C., 1993.